

(1) *Prohibitions on delivery and transfer.* (1) Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), an article of food that has been placed under hold section 801(l) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer subject to hold under section 801(l) of the act.

(2) During the time an article of food that has been refused under section 801(m)(1) of the act is held, the article may not be transferred by any person from the port or the secure facility location until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1) of the act. After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

(m) *Relationship to other admissibility provisions.* A determination that an article of food is no longer subject to hold under section 801(l) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer under hold under section 801(l) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

[68 FR 59070, Oct. 10, 2003; 69 FR 4852, Feb. 2, 2004]

Subpart J—Establishment, Maintenance, and Availability of Records

SOURCE: 69 FR 71651, Dec. 9, 2004, unless otherwise noted.

GENERAL PROVISIONS

§ 1.326 Who is subject to this subpart?

(a) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in § 1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in § 1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food is being offered for or enters interstate commerce.

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

(a) Farms are excluded from all of the requirements in this subpart.

(b) Restaurants are excluded from all of the requirements in this subpart. A restaurant/retail facility is excluded from all of the requirements in this subpart if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.

(c) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel, are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. However, those fishing vessels otherwise engaged in processing fish are subject to all of the requirements in this subpart. For the purposes of this section, “processing” means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel.

(d) Persons who distribute food directly to consumers are excluded from the requirements in § 1.345 to establish and maintain records to identify the

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nontransporter and transporter immediate subsequent recipients as to those transactions. The term “consumers” does not include businesses.

(e) Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in this subpart. However, the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.

(1) For purposes of this section, retail food establishment is defined to mean an establishment that sells food products directly to consumers as its primary function. The term “consumers” does not include businesses.

(2) A retail food establishment may manufacture/process, pack, or hold food if the establishment’s primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers.

(3) A retail food establishment’s primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.

(4) A “retail food establishment” includes grocery stores, convenience stores, and vending machine locations.

(f) Retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. The exclusion is based on the number of full-time equivalent employees at each retail food establishment and not the entire business, which may own numerous retail stores.

(g) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are excluded from all

of the requirements in this subpart with respect to that food while it is under the exclusive jurisdiction of USDA.

(h) Foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of this subpart.

(i) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of this subpart.

(j) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts food are excluded from all of the requirements of this subpart, except §§ 1.361 and 1.363.

(k) Persons who place food directly in contact with its finished container are subject to all of the requirements of this subpart as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of this subpart as to the finished container, except §§ 1.361 and 1.363.

(l) Nonprofit food establishments are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363.

(m) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of this subpart.

(n) Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of this subpart.

§ 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply